❑ **New Filing** ❑ **Update for FWA Identifier: _____**

Department of Health and Human Services (DHHS)
Federalwide Assurance (FWA) for the Protection of Human Subjects
For International Sites

1. Institution Filing Assurance

Legal Name:

City: State/Province: Country:

DHHS Institution Profile File (IPF) code, if known:

Federal Entity Identification Number (EIN), if known:

If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board (IRB) or the Institutional Ethics Committee (IEC), IRB/IEC support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

G Please check here if there are no additional components or alternate names.

Name of Component or Alternate Names Used	City	State or Country

3. Statement of Principles

This Institution assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the following document(s). (*indicate below*)

❑ ***The Declaration of Helsinki***
❑ ***The Belmont Report***
❑ ***Other*** *(please submit copy to OHRP with this Assurance)*

4. Applicability

This Institution assures that all of its activities related to United States (U.S.) federally-conducted or -supported human subject research will comply with a) the **Terms of Assurance for Protection of Human Subjects for Institutions Outside the U.S.** (NOTE: The Terms of Assurance are contained in a separate document on the OHRP website) and b) the following procedural standards:

(*please check one or more of the following)*

- ❑ **45 CFR 46, 21 CFR 50, and 21 CFR 56**
- ❑ **Canadian Tri-Council Policy**
- ❑ **CIOMS International Ethical Guidelines**
- ❑ **ICH-GCP-E6 Sections 1 through 4**
- ❑ **Indian Council of Medical Research**
- ❑ **Other** *(please submit copy to OHRP with this Assurance)*

5. Designation of Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs)

This Institution designates the following IRB(s)/IEC(s) for review of research under this Assurance [*if the IRB(s)/IEC(s) is not previously registered with DHHS or has not provided a membership roster to DHHS, please attach the appropriate IRB registration materials available on the OHRP website*].

NOTE: Reliance on another institution's IRB/IEC or an independent IRB/IEC must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the institutions involved may develop their own agreement. Future designation of other IRB(s)/IEC(s) requires update of the FWA.

DHHS IRB Registration Identifier	**Name of IRB As Registered with DHHS**

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First, Middle, Last Name:
Degrees or Suffix (e.g., MD, PhD):
Institutional Title:
Name of Institution:
Address:
City, State/Province:
Country:

7. <u>Signatory Official (i.e., Official Legally Authorized to Represent the Institution -- cannot be IRB/IEC Chairperson or IRB/IEC member)</u>

I am aware that the Assurance Training Modules on the OHRP website describe the responsibilities that must be fulfilled by the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing all research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s)/IEC(s) designated above are to provide oversight for all research conducted under this Assurance. These IRB(s)/IEC(s) will comply with the **Terms of Assurance** and possess appropriate knowledge of the local context in which this Institution's research will be conducted. I understand that all collaborating institutions engaged in U.S. federally-conducted or -supported human subject research must submit their own Assurance.

All information provided with this Assurance is up to date and accurate. *I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.*

Signature: _____ Date: _____

First, Middle, Last Name:
Degrees or Suffix (e.g., MD, PhD):
Institutional Title:
Name of Institution:
Address:
City, State/Province:
Country:

Telephone: FAX: E-Mail:

8. <u>DHHS Approval</u>

The Federalwide Assurance of Protection for Human Subjects submitted to DHHS by the above Institution is hereby approved.

Assurance Identifier: _____ *Expiration Date:* _____

Signature of DHHS Approving Official: _____ Date: _____
Name:
Address: Assurance Coordinator, DHSP
OHRP – FWA
Office for Human Research Protections
Tower Building
1101 Wooten Parkway, Suite 200
Rockville, MD 20852USA
Phone #: 301-402-_____ Fax #: 301-402-0527 Email: _____@nih.gov